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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,302

09/07/2006

Gad Alon

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EXAMINER

ROBINSON, JAMES MARSHALL

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MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,302	<b>Applicant(s)</b> ALON ET AL.	
	<b>Examiner</b> James M. Robinson	<b>Art Unit</b> 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-12,15,18,20,21,23,28 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-12,15,18,20,21,23,28 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to amendments/arguments filed 07/23/2008. Currently claims 1-7, 9-12, 15, 18, 20, 21, 23, 28, and 33 are pending in the instant application. It is noted that applicant amended claims 1-3, 5, 7, 11, 15, 18, 21, 23, and 28 are amended. The objection to claim 5 is withdrawn. The 35 U.S.C. 112, second paragraph to claim 11 for use of the trademark term VELCRO is withdrawn. It is noted that claims 8, 13-14, 16-17, 19, 22, 14-27, and 29-32 are cancelled. It has come to the attention of the examiner that the rejection of claims 1-7, 12, 20-21, and 33 was rejected under 35 USC 102(b), please note the statement of statutory basis of the 102(b) rejection on page 3, numeral "4". However numeral "5", page 3 of the non-final rejection states "claims 1-7, 12, 20-21, and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by John Michael's Corner". The (a) was a typographical error. Examiner intended to reject claims 1-7, 12, 20-21, and 33 under 35 U.S.C. 102(b) evidenced by inclusion of the statement of statutory basis as noted above.

### ***Response to Arguments***

1. Applicant's arguments filed 07/23/2008 have been fully considered but they are not persuasive. With respect to applicants position that Michael is directed to a spiral shaped lower leg orthosis that is effective at preventing foot drop...but that nothing in Michael mentions or suggests preventing knee hyper-extension or a posting angle that deviates from 90 degrees (see Remarks page 6) examiner respectfully disagrees. Regarding knee-hyperextension, the structure of the device disclosed by Michael meets

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the claimed limitations. Therefore the device of Michael is capable of functioning in the same manner as claimed by applicant to function to inhibit hyperextension of the wearer's knee, which has been considered by examiner as a functional recitation. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a posting angle that deviates from 90 degrees" [see Remarks pg. 6]) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). A "posting angle" is not claimed. Please note examiner's rejection to claim 1 below, specifically in reference to the "axis of the spiral-shaped lower leg portions are disposed at an acute angle".

### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ascension angle

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must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: an acute angle (see claim 1) is not recited in the specification.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7, 9-12, 15, 18, 20, 21, 23, 28, and 33 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Adequate support does not exist in the specification for the recitation "disposed at an acute angle with respect to one another and wherein a difference between the angle and 90 degrees is greater than about 2 degrees to inhibit hyperextension of the wearer's knee". The only "difference" supported by the specification is in reference to a "heel-toes differential" [0045] or a "height differential" [0053]. However a difference in reference to the axis of the spiral-shaped lower leg portion is not supported by the specification. Further, the claim recitation "a difference between an angle...is greater than about 2 degrees to inhibit hyperextension of the wearer's knee" is not supported by the specification. The specification [00049] recites the "the posting angle is between 10 degrees and 15 degrees, which eliminates knee-hyperextension for a large number of wearers".

***Claim Rejections - 35 USC § 102***

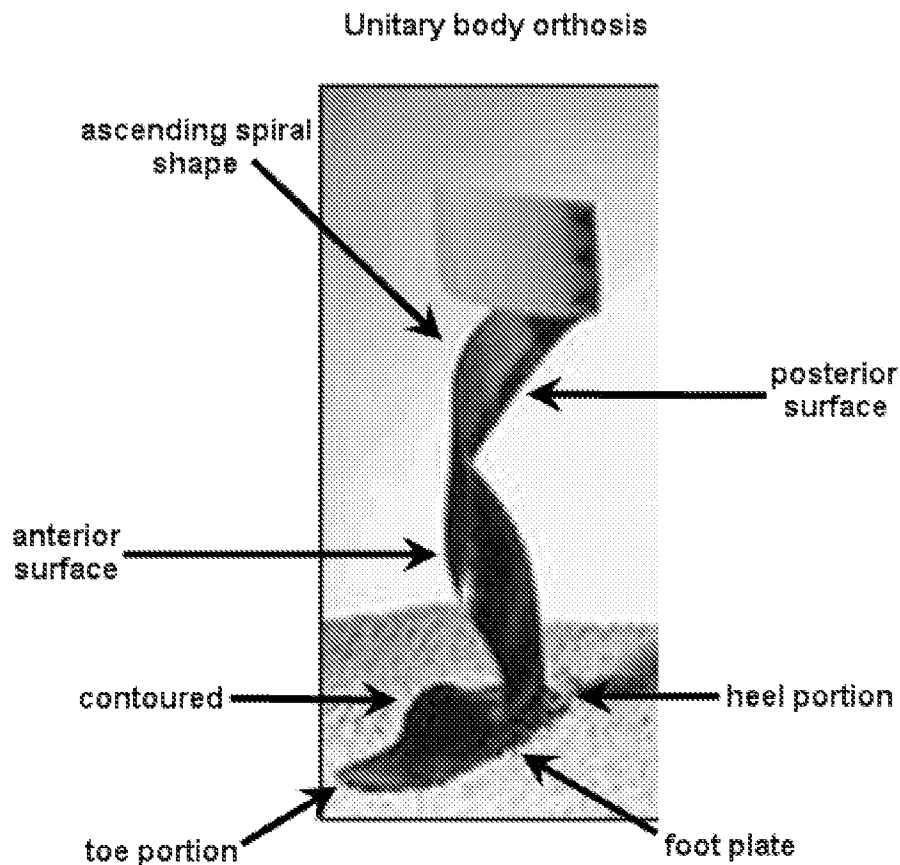
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-7, 12, 20-21, & 33** are rejected under 35 U.S.C. 102(b) as being anticipated by **John Michael's Corner [online] Retrieved from <http://www.oandp.com/news/jmcorner/2000-08/8.asp>**.

**Regarding claim 1**, Michael discloses an orthosis comprising a single, unitary body comprising: a generally spiral-shaped lower leg portion that, when the orthosis is worn by a wearer, covers at least a portion of the anterior surface of the wearer's lower leg and at least a portion of a posterior surface of the wearer's lower leg; and a foot plate portion that, when the orthosis is worn, accepts the wearer's foot, wherein the lower leg portion is configured to spiral upward from the foot plate portion and make contact with an anterior surface of the wearer's lower leg prior to making contact with a posterior surface of the wearer's lower leg as the lower leg portion ascends (see fig. below).

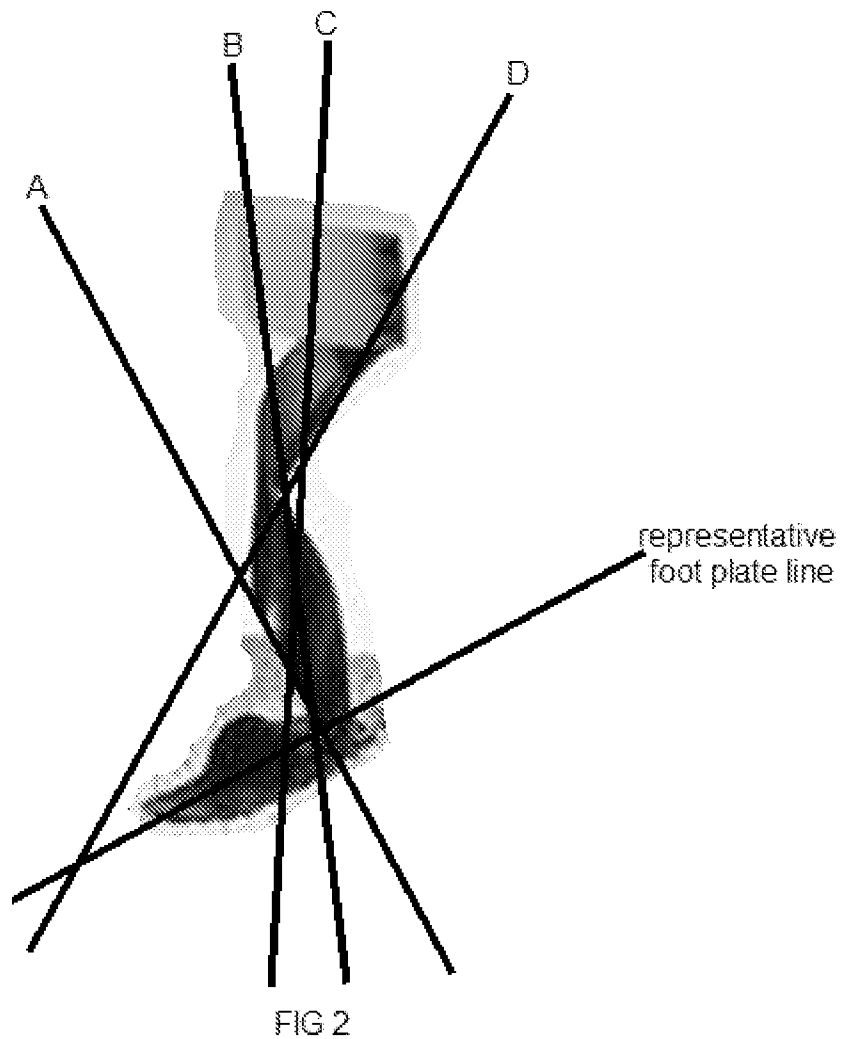


Further, Michael discloses wherein the foot plate portion and an axis of the spiral-shaped lower leg portion are disposed at an acute angle with respect to one another and wherein a difference between the angle and 90 degrees is greater than about 2 degrees to inhibit hyperextension of the wearer's knee. Please refer to figure 2 below for illustrative purposes. Any one of the lines labeled A, B, C, and D can possibly be referred to as "an axis of the spiral-shaped lower leg portion". It is clear that an acute angle wherein a difference between the angle and 90 degrees is greater than about 2 degrees is disclosed. Further, it should be noted that each of these lines A, B, C, and D



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actually create two angles. If one of these angles is obtuse, it is inherent that its supplementary angle is acute.



**Regarding claim 2,** Michael discloses an orthosis wherein the foot plate portion comprises an anterior section; and a posterior section, wherein, when the orthosis is worn, the wearer's toes contact the anterior section and the wearer's heel contacts the posterior section, and wherein the foot plate portion is optionally contoured to

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complement at least a portion of a plantar surface of the wearer's foot so as to permit the wearer to wear shoes or sandals (see fig. above).

**Regarding claim 3**, Michael discloses an orthosis wherein: the unitary body is capable of transferring mechanical energy while the wearer is walking; the unitary body is capable of using the transferred mechanical energy to stop the wearer's knee from hyperextending; and the unitary body is capable of maintaining the wearer's foot in a position that allows the wearer's heel to contact the ground before the rest of the wearer's foot. When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions are presumed to be inherent.

**Regarding claim 4**, Michael discloses an orthosis wherein the lower leg portion comprises an ascending section that extends from the foot plate section and curves toward the anterior surface of the wearer's lower leg to form a shin section (see fig. above).

**Regarding claim 5**, Michael discloses an orthosis wherein, from the shin section, the lower leg portion spirals around at least a portion of a lateral surface of the wearer's lower leg and transitions into a calf section (see fig. above).

**Regarding claim 6**, Michael discloses an orthosis wherein the calf section terminates in an upper end of the lower leg portion and begins to spiral back toward the anterior surface of the wearer's lower leg.

**Regarding claim 7**, Michael discloses an orthosis wherein the ascension angle at which the lower leg portion spirals upward gradually decreases as the lower leg

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portion nears the calf of the wearer (see fig. above). The degree of the angle of the spiral at the calf is less than the degree of the angle at the shin. This change in the degree of the angle is gradual.

**Regarding claim 12** Michael discloses an orthosis wherein the unitary body is made of composite carbon fiber (paragraph 1, line 3).

**Regarding claim 20** Michael discloses an orthosis wherein the foot plate portion comprises a front edge and a back edge (refer to figure above), wherein the back edge is elevated above the front edge (the contour of the foot plate creates the elevation).

**Regarding claim 21** Michael discloses an orthosis wherein the foot plate portion comprises a front edge and a back edge (refer to figure above), wherein a first distance between the back edge and ground level is about twice a second distance between the front edge and ground level (the contour of the foot plate creates the distance between the back edge and the ground level).

**Regarding claim 33**, Michael discloses an orthosis wherein the foot plate portion has a substantially flat outer surface (see fig. above).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

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matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**2. Claims 9-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over **John Michael's Corner [online] Retrieved from <http://www.oandp.com/news/jmcorner/2000-08/8.asp>** in view of **Ingimundarson et al. (US 2005/0234378)**.

**Regarding claims 9-11**, Michael teaches a unitary body orthosis comprising an inner surface. Michael fails to teach an orthosis comprising a lining material attached to an inner surface; wherein the lining material is removably attached to the inner surface; wherein the lining material is removably attached to the inner surface using Velcro (hook and loop).

However, Ingimundarson teaches an orthosis comprising a lining material attached to an inner surface; wherein the lining material is removably attached to the inner surface; wherein the lining material is removably attached to the inner surface using hook and loop ([0056]).

To provide the device of the Michael reference with a removably attached lining surface would have been obvious to one of ordinary skill in the art, in view of the teachings of Ingimundarson, since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known

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methods (hook and loop integration) with no change in their respective functions. The combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that inclusion of a removable lining on the inner surface of the orthosis would serve to protect the user's lower leg from irritation caused by the carbon fiber inner surface rubbing on the tissue of the lower leg.

3. **Claims 15, 18, 23, & 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **John Michael's Corner [online] Retrieved from <http://www.oandp.com/news/jmcorner/2000-08/8.asp>**.

**Regarding claims 15 & 18**, Michael substantially discloses the invention as claimed; see rejection to claim 1 above.

Michael fails to disclose wherein the difference between the angle and 90 degrees is between about 7 degrees and about 14 degrees; wherein the difference between the angle and 90 degrees is between about 20 degrees and about 25 degrees.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the angle between about 7-10 degrees and 20-25 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. The range of the angle is obvious to ensure that a user when walking will strike the ground with his foot at the heel followed by the toe.

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**Regarding claim 23**, Michael discloses an orthosis wherein the foot plate portion comprises an anterior section and a posterior section (refer to figure above) wherein a difference in elevation exists between the anterior section and the posterior section as a result of the contour of the foot plate.

Michael fails to explicitly teach the exact difference in elevation being between 0 cm and 3 cm.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the elevation difference between the anterior and posterior of the foot plate to be between 0 cm and 3 cm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

**Regarding claim 28**, Michael discloses an orthosis wherein the foot plate portion comprises a medial side and a lateral side having a difference in elevation as a result of the contour in the foot plate.

Michael fails to explicitly teach the difference in elevation between the medial side and the lateral side is greater than 0 millimeters and no greater than about 10 millimeters.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to design the elevation difference between the medial and lateral side of the foot plate to be between 0 mm and 10 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Robinson whose telephone number is 571-270-3867. The examiner can normally be reached on Monday - Friday 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772